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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,952	03/11/2004	Marina Lowen	SHLI-038-002	4856
22428	7590	10/26/2006		
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER AFREMOVA, VERA	
			ART UNIT	PAPER NUMBER
			1657	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/797,952	<b>Applicant(s)</b> LOWEN ET AL.	
	<b>Examiner</b> Vera Afremova	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-7 and 16-21, in the reply filed on 8/15/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement between claims drawn to product and method of using the product, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Please, note that in the last office action the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 8-15 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention.

Claims 1-7 and 16-21 are under examination.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita et al. ("New and better protocols for a short-term Caco-2 cells culture system". Journal of Pharmaceutical Sciences. March 2002. Vol. 91, No. 3, pages 669-679) in the light of evidence by Barka et al. (Journal of Histochemistry and Cytochemistry. Novembre 2000. Vol. 48, pages 1453-1460.).

Claims are directed to a composition for culturing intestinal epithelial cells and to a method of making a composition for culturing intestinal epithelial cells wherein the composition comprising a cell culture medium, serum, non-essential amino acids, transferrin, insulin, epithelial growth factor (EGF), butyrate, hydrocortisone, progesterone and testosterone. Some claims are further drawn to incorporation of non-essential amino acids (NEAA) at concentration 1% in the medium and to incorporation of fetal bovine serum in amounts 5-20% in the medium.

The reference by Yamashita et al. teaches a culture system kit or a composition for culturing intestinal epithelial cells that comprises basic culture medium BCM, differentiation medium DM and butyrate (page 671, table 1, protocol ). The BCM contains DMEM supplemented with 1% NEAA and 10% FBS (page 670, col. 1, par. 3). The DM contains MITO extender (page 671, col. 2). The MITO extender contains transferrin, insulin, epithelial growth factor (EGF), hydrocortisone, progesterone and testosterone as evidenced by Barka et al. (see section materials and methods). Thus, the whole culture kit designed for culturing intestinal epithelial cells (page 671, table 1) is considered to be a composition comprising identical components as required for the claimed composition. Combining ingredients in the culture kit or mixing ingredients during culturing protocols practiced under sterile conditions is considered to be a method of making composition by admixing ingredients under sterile conditions within the

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meaning of the claims.

Thus, the reference by Yamashita et al. anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita et al. ("New and better protocols for a short-term Caco-2 cells culture system". Journal of Pharmaceutical Sciences. March 2002. Vol. 91, No. 3, pages 669-679), Barka et al. (Journal of Histochemistry and Cytochemistry. November 2000. Vol. 48, pages 1453-1460.) and US 5,712,163 (Parenteau et al.).

Claims 1, 2, 6, 16 and 17 as explained above. Some claims are further drawn to the use of particular concentrations of transferrin, insulin, epithelial growth factor (EGF), butyrate, hydrocortisone, progesterone and testosterone in the culture system for culturing epithelial cells.

The reference by Yamashita et al. teaches a culture system composition for culturing intestinal epithelial cells that comprises a basic cell culture medium DMEM, serum, non-essential amino acids, butyrate, transferrin, insulin, epithelial growth factor (EGF), hydrocortisone, progesterone and testosterone as evidenced by the reference by Barka et al.

The references by Yamashita et al and by Barka et al. are silent about concentration of some supplements and hormones. However, US 5,712,163 teaches culture media and culture

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systems for epithelial cells comprising supplements such as transferrin, insulin, EGF and hormones including hydrocortisone and progesterone at concentrations within the presently claimed ranges (column 5, lines 25-60; column 17, lines 25-30; column 19, lines 25-43). Thus, the use of particular concentrations as encompassed by the presently claimed invention is obvious as intended for making culture composition and/or kit for culturing epithelial cells including intestinal epithelial cells.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to include supplements and hormones at concentrations as required by the present invention with a reasonable expectation of success in obtaining culture composition suitable for growth and differentiation of for epithelial cells as adequately suggested by the prior art of record. One of skill in the art would have been motivated to use known components at their suggested concentrations for the expected benefits in culturing and differentiation epithelial cells for the expected benefits in producing cells suitable for grafting and for testing pharmaceuticals. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

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The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

October 24, 2006

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal stroke extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER